

# Dr Reddy's On Digitization Amid COVID-19, 'Lights-Out' Manufacturing

*Remote Inspections Were 'Good Learning'*

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## *Executive Summary*

Dr Reddy's global head of quality outlines how the company leveraged digitization to keep plants running at full throttle amid the pandemic and went on to operationalize a site for remdesivir designed as a "lights out" facility. Certain facilities at the Indian firm have also undergone remote inspections by major regulatory agencies.



GANADHISH KAMAT, GLOBAL HEAD OF QUALITY, DR REDDY'S LABORATORIES

COVID-19 brought with it unprecedented change on the operational front for pharma, with firms accelerating digitization and adopting and scaling a bevy of new technologies to keep plants chugging along and employees safe, while also also requiring gearing for remote inspections by regulators.

Front-line Indian companies such as [Dr. Reddy's Laboratories Ltd.](#) may have had a head-start, having opted for digitization initiatives even before the pandemic struck. The future may see the Hyderabad-based firm lean more towards “lights-out” fully automated facilities, extensive use of artificial intelligence (AI) and machine learning (ML) to further improve quality and efficiency.

Interestingly, Dr. Reddy's began operations at its first site designed for lights-out manufacturing, for the antiviral remdesivir, which it licensed from originator [Gilead Sciences, Inc.](#) last year.

In an interview with *Scrip*, Ganadhish Kamat, global head of quality at Dr. Reddy's, said that while the company already had software solutions such as Manufacturing Execution Systems (MES) and Laboratory Information Management System (LIMS) in place, it was now moving to the next level and ensuring that all the data generated and “scattered across places in different systems” is effectively tapped into.

“We are now utilizing data lakes to bring all this data together and we are using AI/ML kinds of technologies to draw useful information from all the data which is available, which will help us in improving quality as well as efficiency,” Kamat explained.

Solutions like MES typically ensure that quality and efficiency are built into the manufacturing process and are proactively and systematically enforced; it helps companies' lower risks and reduce timelines and costs, while providing real-time information on requirement changes.

## Machine-Vision Algorithms

Dr. Reddy's has also been using automatic data acquisition from manufacturing and testing equipment and machine-vision algorithms that can conduct automatic quality inspection and control using predictive algorithms.

“We are already using this vision technology for a few of our activities like inspections of our tablets/capsules/ ampoules; we have been using vision-based inspection even before COVID-19,” Kamat noted.

The focus on automation and digitization also meant that during the early peak of the pandemic, the company could use these technologies to its advantage and many activities not required to be performed on-site could be done remotely by giving people secure access.

The executive now believes that some of these options allowing people to work from home could continue to be available even in a post-COVID-19 world. The flexibilities may also be useful for women employees, who may find it difficult to come to work every day post-childbirth, which would also be in sync with Dr. Reddy's overall goal of having a diversified workforce, he added.

The Indian company for the third time featured in the 2020 Bloomberg Gender Equality Index for its commitment towards the cause.

Technology advances notwithstanding, Kamat outlined how the company's senior leadership increased their presence on the shop floor in the early part of the pandemic to keep employee morale high and workflows stable during the testing phase, which was marked by a fear of traveling to work and potentially contracting COVID-19.

“All the management committee members including me, the heads of HR [human resources] and operations started spending a lot of time on the shop floor so that our presence also gave people confidence that it's not that we are only asking them to come [to work], but we are leading from the front,” he explained. For facilities in more remote locations, “constant contact” through video conferencing and team meetings ensured that employees remained motivated.

Dr. Reddy's has over 20 manufacturing facilities in India and abroad, including at sites in the US and UK. Like some other Indian firms, Dr Reddy's has ongoing operations benchmarking efforts versus other peer manufacturing sites and also participates in McKinsey's proprietary POBOS database, which benchmarks cost, productivity, quality, and service performance of plants globally.

“Based on that we have set a target that by 2025 we will be in the top decile of POBOS and we have an operational excellence program in place, which is working in this direction,” Kamat said.

Industry benchmarks like POBOS also track predictive metrics such as right-first-time rate, yield, corrective and preventive action [CAPA] implementation time, investigation cycle time and recurring deviations.

## Lights-Out Facility

Kamat referred to the firm's new site manufacturing remdesivir in Vizag, India as having been designed as a lights-out facility, while more recently a quality control lab at the company had also achieved similar automation status.

“We launched remdesivir in record time. This was the first such site but we are clear that any future facility that will be coming up, it will possibly be the same type of plan,” the executive said.

Such automated plants may not be as common in India as in some parts of the West, where labor costs are comparatively high, though Indian firms are now catching up, he added.

In June last year, Dr. Reddy's announced a non-exclusive licensing pact with Gilead to register, manufacture and sell remdesivir for the potential treatment of COVID-19 countries including India. In early September 2020, the Indian company launched its version as Redyx in India.

## Remote Audits

Meanwhile, Dr. Reddy's appears to have successfully gone through a handful of remote plant audits by agencies including the UK MHRA, China FDA and Russia's regulator, Kamat describing the experience as "good learning". He indicated that when the pandemic first struck, the company began thinking ahead about how to gear up for such potential inspections.

"We created infrastructure based on our own assumptions, including that we should be able to share a lot of data and documents electronically," he explained.

Dr. Reddy's created a platform for sharing that kind of data, a conferencing system to ensure that if an inspector wanted to "talk to five people together" they could do so, procured wi-fi-enabled cameras and created a high bandwidth network so there was no disruption in such interactive sessions.

"So we created all the facilities even before and the few inspections that went through were very successful."

Earlier this year, the European Directorate for the Quality of Medicines & HealthCare (EDQM) initiated a remote inspections pilot scheme focused on drug manufacturers in India. (Also see "[European Inspectors Spot GMP Deficiencies In India During 'Virtual Tours'](#)" - Pink Sheet, 2 Feb, 2021.)

Kamat also noted that the US Food and Drug Administration had been relying on records requests in lieu of inspections using Form 4003, with Dr. Reddy's also having received such requests at some sites. He hoped that the agency would consider remote inspections in due course once guidelines are in place. (Also see "[Drug Manufacturers Beg US FDA To Inspect Facilities, But Still Find Difficulties](#)" - Pink Sheet, 1 Mar, 2021.)

The FDA is said to be exploring using tools such as live stream video for inspecting sites they cannot visit in person. The agency is reported to be "reviewing and drafting a guidance document" in that space. (Also see "[US FDA Mulls Possibility Of Preannouncing Post-COVID Domestic Surveillance Inspections](#)" - Pink Sheet, 15 Mar, 2021.)